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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/486,266 05/03/00 HILLE

T FLA-0035

EXAMINER

HM12/1023

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GHALI, I

ART UNIT

PAPER NUMBER

1615

DATE MAILED:

10/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/486,266	Applicant(s) HILLE ET AL.	
	Examiner Isis Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/4/2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-33,35-39,41-49 and 52-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-33,35-39,41-49 and 52-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- | | |
|---|--|
| 15) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 18) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 16) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 19) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 17) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 20) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

The receipt is acknowledged of applicants' revocation of prior power of attorney and new power of attorney, filed 7/5/2001; substitute specification and amendment B, both filed 8/31/2001; and supplemental reply and fee, filed 9/4/2001.

Claims 34, 40, 50 and 51 have been canceled, and claims 58-66 have been added per applicants' amendment B in Paper No. 11.

Claims 22-33, 35-39, 41-49, and 52-66 are included in the prosecution.

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the substitute description, as amended: 10, 12, 14, 16, 18, and 20. Correction is required.

Claim Objections

2. Claims 52, 56, 65 and 66 are objected to because of the following informalities: the claims are dependent from canceled claims 51, 40 and 34, consequently. Appropriate correction is required.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 22-33, 35-39, 41-49, and 52-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over any of US 5,240,711 ('711), US 4,390,520 ('520), or US 5,225,199 ('199) each by itself or in combination.

US '711 disclosed a transdermal therapeutic system for controlled release of buprenorphine comprising a backing, pressure sensitive adhesive reservoir and a removable protective layer. The backing is impermeable to the active ingredients and

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flexible (elastic) and may be coated by polymeric substrate. The reservoir layer consisting preferably from polyvinylpyrrolidone. The transdermal system is produced by spreading the active substance containing solution on the backing and punching after drying. See abstract; col.3, lines 9-19, 51-52; col.4, line 67 till col.5, line 5.

US '520 disclosing a transdermal analgesic adhesive comprising a pressure sensitive adhesive layer containing the drug and a flexible substrate (backing). The backing expands on one direction and prepared from polyethylene and having a moisture permeability from 5 to 2000 g/m²/hr. The adhesive layer comprising vinyl pyrrolidone. See the abstract; col.2, lines 49-68; col.3, lines 1-2, 55-56.

US 199 is teaching a pharmaceutical plaster comprising film layer (represents the backing), adhesive layer containing the drug such as hormone or buprenorphine, and another covering layer removed before use. The film layer has elongation (elasticity) of 30 to 150 % and made of polyethylene terephthalate. See the abstract; col.3, lines 58-61; col.5, lines 34-35.

No superior and unexpected results were established showing the criticality of the claimed ranges of wrap thread and weft thread. It is within the skill in the art to have differentiated marking elements.

Accordingly, it would have been obvious to one having ordinary skill in the art at the time of the invention to deliver transdermal therapeutic system comprising adhesive reservoir layer containing the active ingredient; a release liner; and a uni-directional elastic backing disclosed by US '520 and adjusting the elasticity of the backing to that percentage disclosed by US '199, motivated by the teaching of US '520 and US '199

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that the elasticity of the backing prevents the sense of tension from the skin, with reasonable expectation of success of delivering a comfortable patch.

6. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 5,846,558 disclosed ionically conductive adhesive used in medical devices.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis Ghali whose telephone number is (703) 305-4048. The examiner can normally be reached on Monday through Thursday from 7:00 AM to 5:30 PM, Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page, can be reached on (703) 308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Isis Ghali
Examiner
Art Unit 1615


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600